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MULTI-CHANNEL NON-INVASIVE TISSUE OXIMETER

This invention relates generally to *in vivo* spectrophotometric examination and monitoring of selected blood metabolites or constituents in human and/or other living subjects, *e.g.*, medical patients, and more particularly to spectrophotometric oximetry, by transmitting selected wavelengths (spectra) of light into a given area of the test subject, receiving the resulting light as it leaves the subject at predetermined locations, and analyzing the received light to determine the desired constituent data based on the spectral absorption which has occurred, from which metabolic information such as blood oxygen saturation may be computed for the particular volume of tissue through which the light spectra have passed.

A considerable amount of scientific data and writings, as well as prior patents, now exist which is/are based on research and clinical studies done in the above-noted area of investigation, validating the underlying technology and describing or commenting on various attributes and proposed or actual applications of such technology. One such application and field of use is the widespread clinical usage of pulse oximeters as of the present point in time, which typically utilize sensors applied to body extremities such as fingers, toes, earlobes, *etc.*, where arterial vasculature is in close proximity, from which arterial hemoglobin oxygenation may be determined non-invasively. A further and important extension of such technology is disclosed and discussed in U.S. Patent No. 5,902,235, which is related to and commonly owned with the present application and directed to a non-invasive spectrophotometric cerebral oximeter, by which blood oxygen saturation in the brain may be non-invasively determined through the use of an optical sensor having light emitters and detectors that is applied to the forehead of the patient. Earlier patents commonly owned with the '235 patent and the present one pertaining to various attributes of and applications for the underlying technology include Nos. 5,139,025; 5,217,013; 5,465,714; 5,482,034; and 5,584,296.

The cerebral oximeter of the aforementioned '235 patent has proved to be an effective and highly desirable clinical instrument, since it provides uniquely important medical information with respect to brain condition (hemoglobin oxygen saturation within the brain, which is directly indicative of the single most basic and important life parameter, *i.e.* brain vitality). This information was not previously available, despite its great importance, since there really is no detectable arterial pulse within brain tissue itself with respect to which pulse oximetry could be utilized even if it could be

effectively utilized in such an interior location (which is very doubtful), and this determination therefore requires a substantially different kind of apparatus and determination analysis. In addition, there are a number of uniquely complicating factors, including the fact that there is both arterial and venous vasculature present in the skin and underlying tissue through which the examining light spectra must pass during both entry to and exit from the brain, and this would distort and/or obscure the brain examination data if excluded in some way. Furthermore, the overall blood supply within the skull and the brain itself consists of a composite of arterial, venous, and capillary blood, as well as some pooled blood, and each of these are differently oxygenated. In addition, the absorption and scatter effects on the examination light spectra are much greater in the brain and its environment than in ordinary tissue, and this tends to result in extremely low-level electrical signal outputs from the detectors for analysis, producing difficult signal-to-noise problems.

Notwithstanding these and other such problems, the cerebral oximeter embodying the technology of the aforementioned issued patents (now available commercially from Somanetics Corporation, of Troy, Michigan) has provided a new type of clinical instrument by which new information has been gained relative to the operation and functioning of the human brain, particularly during surgical procedures and/or injury or trauma, and this has yielded greater insight into the functioning and state of the brain during such conditions. This insight and knowledge has greatly assisted surgeons performing such relatively extreme procedures as carotid endarterectomy, brain surgery, and other complex procedures, including open-heart surgery, *etc.* and has led to a greater understanding and awareness of conditions and effects attributable to the hemispheric structure of the human brain, including the functional inter-relationship of the two cerebral hemispheres, which are subtly interconnected from the standpoint of blood perfusion as well as that of electrical impulses and impulse transfer.

BRIEF SUMMARY OF INVENTION

The present invention results from the new insights into and increased understanding of the human brain referred to in the preceding paragraph, and provides a methodology and apparatus for separately (and preferably simultaneously) sensing and quantitatively determining brain oxygenation at a plurality of specifically different locations or regions of the brain, particularly during surgical or other such traumatic conditions, and visually displaying such determinations in a directly comparative

manner. In a larger sense, the invention may also be used to monitor oxygenation (or other such metabolite concentrations or parameters) in other organs or at other body locations, where mere arterial pulse oximetry is a far too general and imprecise examination technique.

Further, and of considerable moment, the invention provides a method and apparatus for making and displaying determinations of internal metabolic substance, as referred to in the preceding paragraph, at a plurality of particular and differing sites, and doing so on a substantially simultaneous and continuing basis, as well as displaying the determinations for each such site in a directly comparative manner, for immediate assessment by the surgeon or other attending clinician, on a real-time basis, for direct support and guidance during surgery or other such course of treatment.

In a more particular sense, the invention provides a method and apparatus for spectrophotometric *in vivo* monitoring of blood metabolites such as hemoglobin oxygen concentration in any of a preselected plurality of different regions of the same test subject and on a continuing and substantially instantaneous basis, by applying a plurality of spectrophotometric sensors. In a more particular sense, the invention provides a method and apparatus for spectrophotometric *in vivo* monitoring of blood metabolites such as hemoglobin oxygen concentration in any of a preselected plurality of different regions of the same test subject and on a continuing and substantially instantaneous basis, by applying a plurality of spectrophotometric sensors to the test subject at each of a corresponding plurality of testing sites, coupling each such sensor to a control and processing station, operating each such sensor to spectrophotometrically irradiate a particular region within the test subject associated with that sensor, detecting and receiving the light energy resulting from such spectrophotometric irradiation for each such region, conveying signals corresponding to the light energy so received to the control and processing station, analyzing the conveyed signals to determine preselected blood metabolite data, and displaying the data so obtained from each of a plurality of such testing sites and for each of a plurality of such regions, in a region-comparative manner.

The foregoing principal aspects and features of the invention will become better understood upon review of the ensuing specification and the attached drawings, describing and illustrating preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a pictorial representation of a patient on whom apparatus in accordance with the invention is being used;

Fig. 2 is a fragmentary plan view of a typical sensor used in accordance with the invention;

Fig. 3 is an enlarged, fragmentary, pictorial cross-sectional view of a human cranium, showing the sensors of Fig. 2 applied and in place, generally illustrating both structural and functional aspects of the invention;

Fig. 4 is a front view of a typical control and processing unit for use in the invention, illustrating a preferred display of data determined in accordance with the invention;

Figs. 5, 6, and 7 are graphs representing data displays obtained in accordance with the invention which represent actual surgical procedure results from actual patients;

Fig. 8 is a pictorialized cross-sectional view representing a test subject on which a multiplicity of sensors are placed in sequence, further illustrating the multi-channel capability of the present invention;

Fig. 9 is a schematic block diagram generally illustrating the componentry and system organization representative of a typical implementation of the invention; and

Fig. 10 is a pictorialized cross-sectional view similar to Fig. 8, but still further illustrating the multi-channel capability of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENT

Fig. 1 depicts an illustrative patient 10 on whom an instrument 12 in accordance with the present invention is being employed. As illustrated, the forehead 14 of patient 10 has a pair of sensors 16, 116 secured to it in a bilateral configuration, *i.e.*, one such sensor on each side of the forehead, where each may monitor a different brain hemisphere. Each of the sensors 16, 116 is connected to a processor and display unit 20 which provides a central control and processing station (sometimes hereinafter, referred to as the "oximeter") by a corresponding electrical cable 16A, 116A, which join one another at a dual-channel coupler/pre-amp 18, 118 and then (preferably) proceed to the control and processor 20 as an integrated, multiple-conductor cable 22. As will be understood, the electrical cables just noted include individual conductors for energizing light emitters and operating the related light detectors contained in sensors 16, 116, all as referred to further hereinafter and explained in detail in the various prior patents.

The general nature of a typical structure and arrangement for the sensors 16,116 (which are identical in nature and which may if desired be incorporated into a single physical unit) is illustrated in Fig. 2, and comprises the subject matter of certain of the earlier patents, in particular Nos. 5,465,714; 5,482,034; 5,584,296; and 5,795,292, wherein the structure and componentry of preferred sensors are set forth in detail. For present purposes, it is sufficient to note that the sensors 16, 116 include an electrically actuated light source 24 for emitting the selected examination spectra (*e.g.*, two or more narrow-bandwidth LEDs, whose center output wavelengths correspond to the selected examination spectra), together with a pair of light detectors 26, 28 (*e.g.*, photodiodes) which are preferably located at selected and mutually different distances from the source 24. These electro-optical (*i.e.*, "optode") components are precisely positioned upon and secured to, or within, a sensor body having a foam or other such soft and conformable outer layer which is adhesively secured to the forehead (or other desired anatomical portion) of the patient 10, as generally illustrated in Fig. 1, and individual electrical conductors in cables 16A, 116A provide operating power to the sources 24 while others carry output signals from the detectors 26, 28, which are representative of detected light intensities received at the respective detector locations and must be conveyed to the processor unit 20, where processing takes place.

Figure 3 generally illustrates, by way of a pictorialized cross-sectional view, the sensors 16, 116 in place upon the forehead 14 of the patient 12. As illustrated in this figure, the cranial structure of patient 12 generally comprises an outer layer of skin 30, an inner layer of tissue 32, and the frontal shell 34 of the skull, which is of course bone. Inside the skull 34 is the Periosteal Dura Mater, designated by the numeral 36, and inside that is the brain tissue 38 itself, which is comprised of two distinct hemispheres 38´, 38´´ that are separated at the center of the forehead inwardly of the superior sagital sinus by a thin, inwardly-projecting portion 36a of the Dura 36. Thus, in the arrangement illustrated in Fig. 3, sensor 16 accesses and examines brain hemisphere 38´´, while sensor 116 does the same to brain hemisphere 38´.

As explained at length in various of the above-identified prior patents, the preferred configuration of sensors 16, 116 includes both a "near" detector 26, which principally receives light from source 24 whose mean path length is primarily confined to the layers of skin, tissue, skull, *etc.*, outside brain 38, and a "far" detector 28, which receives light spectra that have followed a longer mean path length and traversed a

substantial amount of brain tissue in addition to the bone and tissue traversed by the "near" detector 26. Accordingly, by appropriately differentiating the information from the "near" (or "shallow") detector 26 (which may be considered a first data set) from information obtained from the "far" (or "deep") detector 28 (providing a second such data set), a resultant may be obtained which principally characterizes conditions within the brain tissue itself, without effects attributable to the overlying adjacent tissue, *etc.* This enables the apparatus to obtain metabolic information on a selective basis, for particular regions within the test subject, and by spectral analysis of this resultant information, employing appropriate extinction coefficients, *etc.* (as set forth in certain of the above-identified patents), a numerical value, or relative quantified value, may be obtained which characterizes metabolites or other metabolic data (*e.g.*, the hemoglobin oxygen saturation) within only the particular region or volume of tissue actually examined, *i.e.*, the region or zone generally defined by the curved mean path extending from source 24 to the "far" or "deep" detector 28, and between this path and the outer periphery of the test subject but excluding the analogous region or zone defined by the mean path extending from source 24 to "near" detector 26. As will be understood, particularly in view of Applicant's above-identified prior patents as well as is explained further hereinafter, this data analysis carried out by the "control and processing unit" 20 is accomplished by use if an appropriately programmed digital computer, as is now known by those skilled in the art (exemplified in particular by the Somanetics® model 4100 cerebral oximeter).

The present invention takes advantage of the primarily regional oxygen saturation value produced by each of the two (or more) sensors 16, 116, together with the natural hemispheric structure of brain 38, by use of a comparative dual or other multi-channel examination paradigm that in the preferred embodiment or principal example set forth herein provides a separate but preferably comparatively displayed oxygen saturation value for each of the two brain hemispheres 38′, 38′′. Of course, it will be understood that each such regional index or value of oxygen saturation is actually representative of the particular region within a hemisphere actually subjected to the examining light spectra, and while each such regional value may reasonably be assumed to be generally representative of the entire brain hemisphere in which it is located, and therefor useful in showing and contrasting the differing conditions between the two such hemispheres of the brain 38, the specific nature and understanding of these hemispheric

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interrelationships and of interrelationships between other and different possible sensor locations relative to each different hemisphere 38´, 38´´ are not believed to be fully known and appreciated as of yet. Consequently, it may be useful or advantageous in at least some cases, and perhaps in many, to employ a more extensive distribution and array of sensors and corresponding inputs to the oximeter 20, such as is illustrated for example in Figure 8.

Thus, as seen in Fig. 8, a more extensive array of sensors 16, 116, 216, *etc.*, may be deployed around the entire circumference of the head or other such patient extremity, for example, each such sensor sampling a different regional area of each brain hemisphere or other such organ or test site and outputting corresponding data which may be contrasted in various ways with the analogous data obtained from the other such sensors for other test site regions. In this regard, it will be appreciated that the extent of each such regional area subjected to examination is a function of a number of different factors, particularly including the distance between the emitter or source 24 and detectors 26, 28 of each such set and the amount of light intensity which is utilized, the greater the emitter/sensor distance and corresponding light intensity, the greater the area effectively traversed by the examining light spectra and the larger the size of the "region" whose oximetric or other metabolic value is being determined.

It may also be possible to use only a single source position and employ a series of mutually spaced detector sets, or individual detectors, disposed at various selected distances from the single source around all or a portion of the perimeter of the subject. Each such single source would actually illuminate the entire brain since the photons so introduced would scatter throughout the interior of the skull (even though being subject to increased absorption as a function of distance traversed), and each such emitter/detector pair (including long-range pairs) could produce information characterizing deeper interior regions than is true of the arrays illustrated in Figs. 3 and 8, for example. Of course, the smaller-region arrays shown in these figures are desirable in many instances, for a number of reasons. For example, the comparative analysis of information corresponding to a number of differing such regions, as represented by the array of Figure 8, lends itself readily to very meaningful comparative displays, including for example computer-produced mapping displays which (preferably by use of differing colors and a color monitor screen) could be used to present an ongoing real-time model which would illustrate blood or even tissue oxygenation state

around the inside perimeter of and for an appreciable distance within a given anatomical area or part. The multiple detector outputs from such a single-source arrangement, on the other hand, would contain information relative to regions or areas deep within the brain, and might enable the determination of rSO_2 values (or other parameters) for deep internal regions as well as the production of whole-brain mapping, by differentially or additively combining the outputs from various selected detectors located at particular points.

The dual or bilateral examination arrangement depicted in Figs. 1 and 3 will provide the highly useful comparative display formats illustrated in Figs. 4, 5, 6, and 7 (as well as on the face of the oximeter 20 shown at the right in Fig. 1), for example. In the arrangement shown in Figs. 1 and 4, each sensor output is separately processed to provide a particular regional oxygen saturation value, and these regional values are separately displayed on a video screen 40 as both a numeric or other such quantified value, constituting a basically instantaneous real-time value, and as a point in a graphical plot 42, 44, representing a succession of such values taken over time. As illustrated, the plots or graphs 42, 44 may advantageously be disposed one above the other in direct alignment, for convenient examination and comparison. While the instantaneous numeric displays will almost always be found useful and desirable, particularly when arranged in the directly adjacent and immediately comparable manner illustrated, the graphical trace displays 42, 44 directly show the ongoing trend, and do so in a contrasting, comparative manner, as well as showing the actual or relative values, and thus are also highly useful.

Graphic displays 42, 44 may also advantageously be arranged in the form shown in Figs. 5, 6, and 7, in which the two such individual traces are directly superimposed upon one another, for more immediate and readily apparent comparison and contrast. Each of the examples shown in Figs. 5, 6, and 7 does in fact represent the record from an actual surgical procedure in which the present invention was utilized, and in each of these the vertical axis (labeled rSO_2) is indicative of regional oxygen saturation values which have been determined, while the horizontal axis is, as labeled, "real time," *i.e.*, ongoing clock time during the surgical procedure involved. The trace from the "left" sensor (number 16 as shown in Figs. 1 and 3), designated by the numeral 42 for convenience, is shown in solid lines in these graphs, whereas the trace 44 from the right-hand sensor 116 is shown in dashed lines. The sensors may be placed on any region of

their respective test areas (*e.g.*, brain hemispheres) provided that any underlying hair is first removed, since hair is basically opaque to the applied light spectra and thus greatly reduces the amount of light energy actually introduced to the underlying tissue, *etc.*

With further reference to Figs. 5, 6, and 7, and also inferentially to Fig. 4, it will be seen that at certain times, (*e.g.*, the beginning and end of each procedure, when the patient's condition is at least relatively normal) there is a certain amount of direct correspondence between the two different hemispheric traces 42, 44, and that in at least these time increments the shape of the two traces is reasonably symmetrical and convergent. An idealized such normal result is shown in Fig. 1, wherein both the numeric values and the curves are basically the same. In each of the procedures shown in Figs. 5, 6, and 7, however, there are times when the detected regional cerebral oxygen saturation differs markedly from one brain hemisphere to the other. This is particularly noticeable in Fig. 6, in which it may be observed that the left hand trace 42 is at times only about one half the height (*i.e.*, value) of the right hand trace 44, reaching a minimal value in the neighborhood of about 35% slightly before real time point 12:21 as compared to the initial level, at time 10:50-11:00, of more than 75%, which is approximately the level of saturation in the right hemisphere at the 12:21 time just noted, when the oxygenation of the left hemisphere had decreased to approximately 35%.

As will be understood, the various differences in cerebral blood oxygenation shown by the superimposed traces of Figs. 5, 6, and 7 occur as a result of measures taken during the corresponding surgical procedures, which in these cases are carotid endarterectomies and/or coronary artery bypass graft (CABG), which are sometimes undertaken as a continuing sequence. In the illustrated examples, Figure 5 represents a sequential carotid endarterectomy and hypothermic CABG, in which the vertical lines along the time axis characterize certain events during surgery, *i.e.*, index line 46 represents the time of the carotid arterial incision, line 48 represent the time the arterial clamp was applied and the shunt opened (resulting in reduced arterial blood flow to the left brain hemisphere), index line 50 represents a time shortly after the shunt was removed and the clamp taken off, and the area from about real time 17:43 to the end of the graph was when the hypothermic brain surgery actually took place, the lowest point (just prior to time 18:23) occurring when the heart-lung machine pump was turned on, and the indices at time 19:43 and 20:23 generally show the time for blood rewarming and pump off, respectively. While illustrative and perhaps enlightening, it is not considered

necessary to give the specifics of the surgical procedures portrayed by the graphical presentations of Figs. 6 and 7, although it may be noted that the procedure of Fig. 6 was a carotid endarterectomy of the left side and that of Fig. 7 was a similar endarterectomy on the right side of a different patient. Sufficient to say that these graphs represent other such surgical procedures and show comparable states of differing hemispheric oxygenation.

The importance and value of the information provided in accordance with the present invention is believed self-apparent from the foregoing, particularly the graphical presentations of and comments provided with respect to Figs. 5, 6, and 7. Prior to the advent of the present invention, no such comparative or hemispheric-specific information was available to the surgeon, who did not in fact have any quantified or accurately representative data to illustrate the prevailing hemispheric brain oxygenation conditions during a surgery. Thus, even the use of a single such sensor (16, 116) on the side of the brain on which a procedure is to be done is highly useful and, as of the present time, rapidly being recognized as essential. Of course, it is considerably more useful to have at least the bilateral array illustrated in Fig. 1, to provide comparative data such as that seen in Figs. 4-7 inclusive.

Figure 9 is a schematic block diagram generally illustrating the componentry and system organization making up a typical implementation of the invention, as shown pictorially in Fig. 1 (to which reference is also made). As shown in Fig. 9, the oximeter 20 comprises a digital computer 50 which provides a central processing unit, with a processor, data buffers, and timing signal generation for the system, together with a keypad interface (shown along the bottom of the unit 20 in Fig. 1), display generator and display 40 (preferably implemented by use of a flat electro-luminescent unit, at least in applications where a sharp monochromatic display is sufficient), as well as an audible alarm 52 including a speaker, and a data output interface 54 by which the computer may be interconnected to a remote personal computer, disk drive, printer, or the like for downloading data, *etc.*

As also shown in Fig. 9, each of the sensors 16, 116 (and/or others, in the multi-site configuration illustrated in Fig. 8) receives timing signals from the CPU 50 and is coupled to an LED excitation current source (56,156) which drives the emitters 24 of each sensor. The analog output signals from the detectors (photodiodes) 26, 28 of each sensor are conveyed to the coupler/pre-amp 18, 118 for signal conditioning (filtering and

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amplification), under the control of additional timing signals from the CPU. Following that, these signals undergo A-to-D conversion and synchronization (for synchronized demodulation, as noted hereinafter), also under the control of timing signals from CPU 50, and they are then coupled to the CPU for computation of regional oxygen saturation rSO_2 data, storage of the computed data, and display thereof, preferably in the format discussed above in conjunction with Figs. 4, 5, 6, and 7. As will be apparent, each sensor (16, 116, *etc.*) preferably has its own signal-processing circuitry (pre-amp, *etc.*) upstream of CPU 50, and each such sensor circuit is preferably the same.

While implementation of a system such as that shown in Fig. 9 is as a general matter well within the general skill of the art once the nature and purpose of the system and the basic requirements of its components, together with the overall operation (as set forth above and hereinafter) have become known, at least certain aspects of the preferred such system implementation are as follows. First, it is preferable that the light emitters 24 (*i.e.*, LEDs) of each of the different sensors 16, 116 *etc.*, be driven out-of-phase, sequentially and alternatingly with one another (*i.e.*, only a single such LED or other emitter being driven during the same time interval, and the emitters on the respective different sensors are alternatingly actuated, so as to ensure that the detectors 26, 28 of the particular sensor 16, 116 then being actuated receive only resultant light spectra emanating from a particular emitter located on that particular sensor, and no cross-talk between sensors takes place (even though significant levels of cross-talk are unlikely in any event due to the substantial attenuation of light intensity as it passes through tissue, which is on the order of about ten times for each centimeter of optical path length through tissue). Further, it is desirable to carefully window the "on" time of the detectors 26, 28 so that each is only active during a selected minor portion (for example, 10% or less) of the time that the related emitter is activated (and, preferably, during the center part of each emitter actuation period). Of course, under computer control such accurate and intricate timing is readily accomplished, and in addition, the overall process may be carried on at a very fast rate.

In a multi-site (multiple sensor) system, such as that shown in Fig. 8, the preferred implementation and system operation would also be in accordance with that shown in Fig. 9, and the foregoing comments regarding system performance, data sampling, *etc.*, would also apply, although there would of course be a greater number of sensors and sensor circuit branches interfacing with computer 50. The same would also

be basically true of a single-source multi-site detector configuration or grouping such as that referred to above, taking into consideration the fact that the detectors would not necessarily be grouped in specific or dedicated "near-far" pairs and bearing in mind that one or more detectors located nearer a source than another detector, or detectors, located further from the source could be paired with or otherwise deemed a "near" detector relative to any such farther detector. In any such multiple-site configuration, it may be advantageous to implement a prioritized sequential emitter actuation and data detection timing format, in which more than one emitter may be operated at the same time, or some particular operational sequence is followed, with appropriate signal timing and buffering, particularly if signal cross-talk is not a matter of serious consideration due to the particular circumstances involved (detector location, size and nature of test subject, physiology, signal strength, *etc.*). As illustrated in Fig. 10, a multi-sensor or multiple sector-emitter array may be so operated, by using a number of different emitter-detector pair groupings, with some detectors used in conjunction with a series of different emitters to monitor a number of differing internal sectors or regions.

A system as described above may readily be implemented to obtain on the order of about fifteen data samples per second even with the minimal detector "on" time noted, and a further point to note is that the preferred processing involves windowing of the detector "on" time so that data samples are taken alternatingly during times when the emitters are actuated and the ensuing time when they are not actuated (*i.e.*, "dark time"), so that the applicable background signal level may be computed and utilized in analyzing the data taken during the emitter "on" time. Other features of the preferred processing include the taking of a fairly large number (*e.g.*, 50) of data samples during emitter "on" time within a period of not more than about five seconds, and processing that group of signals to obtain an average from which each updated rSO_2 value is computed, whereby the numeric value displayed on the video screen 40 is updated each five seconds (or less). This progression of computed values is preferably stored in computer memory over the entire length of the surgical procedure involved, and used to generate the graphical traces 42, 44 on a time-related basis as discussed above. Preferably, non-volatile memory is utilized so that this data will not be readily lost, and may in fact be downloaded at a convenient time through the data output interface 54 of CPU 50 noted above in connection with Fig. 9.

As will be understood, the foregoing disclosure and attached drawings are directed to a single preferred embodiment of the invention for purposes of illustration; however, it should be understood that variations and modifications of this particular embodiment may well occur to those skilled in the art after considering this disclosure, and that all such variations *etc.*, should be considered an integral part of the underlying invention, especially in regard to particular shapes, configurations, component choices and variations in structural and system features. Accordingly, it is to be understood that the particular components and structures, etc. shown in the drawings and described above are merely for illustrative purposes and should not be used to limit the scope of the invention, which is defined by the following claims as interpreted according to the principles of patent law, including the doctrine of equivalents.